

# PATENT COOPERATION TREATY

TRANSLATION

From the  
INTERNATIONAL SEARCHING AUTHORITY

## PCT

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:

Date of mailing (day/month/year) **26.05.2005**

Applicant's or agent's file reference

**301011 TIM**

**FOR FURTHER ACTION**

See paragraph 2 below

International application No.

**PCT/RU2004/000542**

International filing date (day/month/year)

**30.12.2004**

Priority date (day/month/year)

**15.01.2004**

International Patent Classification (IPC) or both national classification and IPC

**A61K35/64, A61P31/12**

Applicant

**CHERNYSH, Sergey Ivanovich**

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/RU

Authorized officer

Facsimile No.

Telephone No.

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INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/RU2004/000542

Box No. I

Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.  
☐ This opinion has been established on the basis of a translation from the original language into the following language \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material  
☐ a sequence listing  
☐ table(s) related to the sequence listing
  - b. format of material  
☐ in written format  
☐ in computer readable form
  - c. time of filing/furnishing  
☐ contained in the international application as filed.  
☐ filed together with the international application in computer readable form.  
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

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International application No.

PCT/RU2004/000542

**Box No. V** Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

**1. Statement**

Novelty (N)	Claims	2-10, 12-19	YES
	Claims	1, 11, 20-24	NO
Inventive step (IS)	Claims		YES
	Claims	2-10, 12-19	NO
Industrial applicability (IA)	Claims	1-24	YES
	Claims		NO

**2. Citations and explanations:**

D1: US 6337093

D2: WO 9706820

D3: G.N. Gornostaev "Nasekomye SSSR", "Mysl",  
Moscow, 1970

D4: WO 9014098

D5: FR 2695392

D6: JP 11098997

D7: RU 99102416

D4-D7 characterise the background art for the given problem.

D1 discloses a pharmaceutical composition for which insects are used as the source for production of the composition, namely peptides (oligo- and polypeptides, proteins), or a mixture of peptides made from the hemolymphs of the insects Calliphora of the order Diptera, a method for production and use thereof for treating viral infections. Furthermore, it is known that active agents can be isolated from body fluids (for example, hemolymph) or synthesised.

D2 discloses compositions for antiviral treatment, including as the active agent an enzyme

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produced from the saliva of insects of the family Ceratopogonidae or Culicidae.

It is known from D3 that the subclass Pterigota belongs to the order Diptera.

In the antiviral preparation according to claim 1, insects of the subclass Pterigota are used as the source for production thereof. Moreover, it is specified in the example given in the description that the preparation is produced from the hemolymph of insects, without disclosing the makeup of the preparation.

Antiviral compositions made of the hemolymph of insects of the Diptera order, or the saliva of insects of the Ceratopogonidae or Culicidae family are known, respectively, from D1 (claims, description pages 2-6) and D2 (claims). Moreover, it is known that these insects belong to the subclass Pterigota, which is confirmed by information known from D3.

Therefore, claim 1 and dependent claim 11, and also claims 20-24 in respect of claims 1 and 11, do not meet the requirement of novelty, because the features of these claims are known from D1 or D2, as the specific known solution anticipates the claimed solution submitted in general form (see PCT International Preliminary Examinations Guidelines, Moscow, 2004, volume 1, page 225 (chapter 12.08)).

Dependent claims 2-10, 12-19 include features characterising the use of insects of different orders, genera and families of the subclass

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Pterigota. However, as the use of insects of the subclass Pterigota is known from D1 and D2, the possibility is obvious to a person skilled in the art of using insects of different orders, genera and families of the Pterigota subclass as a source for producing an antiviral preparation, having pre-selected suitable insects according to a classifier (D3), which does not involve an inventive step.

Therefore, claims 2-10, 12-19 and also claims 20-24 in respect of these claims do not meet the requirement of inventive step.

Claims 1-24 meet the requirement of industrial applicability.

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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

The examiner reminds the applicant that claims shall be fully supported by the description (PCT Article 6). This set of claims has been drafted without taking this requirement into account. The description does not contain information about individual substances (claim 20), equivalents thereof produced by chemical or biological synthesis, derivatives thereof, etc. (claim 21).

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Applicant <b>CHERNYSH, Sergey Ivanovich</b>
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<p>1. This opinion contains indications relating to the following items:</p> <div style="margin-left: 20px;"> <input checked="" type="checkbox"/> Box No. I      Basis of the opinion  <input type="checkbox"/> Box No. II      Priority  <input type="checkbox"/> Box No. III      Non-establishment of opinion with regard to novelty, inventive step and industrial applicability  <input type="checkbox"/> Box No. IV      Lack of unity of invention  <input checked="" type="checkbox"/> Box No. V      Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement  <input type="checkbox"/> Box No. VI      Certain documents cited  <input type="checkbox"/> Box No. VII      Certain defects in the international application  <input checked="" type="checkbox"/> Box No. VIII      Certain observations on the international application         </div> <p>2. <b>FURTHER ACTION</b></p> <p>If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.</p> <p>If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.</p> <p>For further options, see Form PCT/ISA/220.</p> <p>3. For further details, see notes to Form PCT/ISA/220.</p>
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Box No. V	Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		
<b>1. Statement</b>			
Novelty (N)	Claims	2-10, 12-19	YES
	Claims	1, 11, 20-24	NO
Inventive step (IS)	Claims		YES
	Claims	2-10, 12-19	NO
Industrial applicability (IA)	Claims	1-24	YES
	Claims		NO
<b>2. Citations and explanations:</b>			
<p style="margin-left: 40px;">D1: US 6337093</p> <p style="margin-left: 40px;">D2: WO 9706820</p> <p style="margin-left: 40px;">D3: G.N. Gornostaev "Nasekomye SSSR", "Mysl", Moscow, 1970</p> <p style="margin-left: 40px;">D4: WO 9014098</p> <p style="margin-left: 40px;">D5: FR 2695392</p> <p style="margin-left: 40px;">D6: JP 11098997</p> <p style="margin-left: 40px;">D7: RU 99102416</p> <p style="margin-left: 40px;">D4-D7 characterise the background art for the given problem.</p> <p style="margin-left: 40px;">D1 discloses a pharmaceutical composition for which insects are used as the source for production of the composition, namely peptides (oligo- and polypeptides, proteins), or a mixture of peptides made from the hemolymphs of the insects Calliphora of the order Diptera, a method for production and use thereof for treating viral infections. Furthermore, it is known that active agents can be isolated from body fluids (for example, hemolymph) or synthesised.</p> <p style="margin-left: 40px;">D2 discloses compositions for antiviral treatment, including as the active agent an enzyme</p>			

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produced from the saliva of insects of the family Ceratopogonidae or Culicidae.

It is known from D3 that the subclass Pterigota belongs to the order Diptera.

In the antiviral preparation according to claim 1, insects of the subclass Pterigota are used as the source for production thereof. Moreover, it is specified in the example given in the description that the preparation is produced from the hemolymph of insects, without disclosing the makeup of the preparation.

Antiviral compositions made of the hemolymph of insects of the Diptera order, or the saliva of insects of the Ceratopogonidae or Culicidae family are known, respectively, from D1 (claims, description pages 2-6) and D2 (claims). Moreover, it is known that these insects belong to the subclass Pterigota, which is confirmed by information known from D3.

Therefore, claim 1 and dependent claim 11, and also claims 20-24 in respect of claims 1 and 11, do not meet the requirement of novelty, because the features of these claims are known from D1 or D2, as the specific known solution anticipates the claimed solution submitted in general form (see PCT International Preliminary Examinations Guidelines, Moscow, 2004, volume 1, page 225 (chapter 12.08)).

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Pterigota. However, as the use of insects of the subclass Pterigota is known from D1 and D2, the possibility is obvious to a person skilled in the art of using insects of different orders, genera and families of the Pterigota subclass as a source for producing an antiviral preparation, having pre-selected suitable insects according to a classifier (D3), which does not involve an inventive step.

Therefore, claims 2-10, 12-19 and also claims 20-24 in respect of these claims do not meet the requirement of inventive step.

Claims 1-24 meet the requirement of industrial applicability.

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The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

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